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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|------------------|
| 10/666,900   | 09/18/2003  | William F. McKay     | 4002-3376/PC445.00              | 8517             |
| 30565  | 7590        | 11/29/2006           |                                 |                  |
| WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP<br>111 MONUMENT CIRCLE, SUITE 3700<br>INDIANAPOLIS, IN 46204-5137 |             |                      |                                 |                  |
|  |             |                      | EXAMINER<br>PELLEGRINO, BRIAN E |                  |
|  |             |                      | ART UNIT<br>3738                | PAPER NUMBER     |

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/666,900

Applicant(s)

MCKAY ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12, 16-30, 34, 35, 38 and 42-48 is/are pending in the application.
- 4a) Of the above claim(s) 5-11, 20-26 and 28-30 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42-48 is/are allowed.
- 6) ☒ Claim(s) 1-4, 12, 16-19, 27, 34, 35 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-19,27,38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: pulling the drawstring to fold the length of natural tissue.

Claim 38 recites the limitation "said length of braided natural tissue" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3,16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Muhanna (6936070). Muhanna discloses that natural tissue, such as pericardium can be used as an intervertebral implant, col. 4, lines 35-37,51-54. Regarding claim 16, Muhanna also discloses a method to repair all or part of the disc by inserting in the intervertebral disc natural tissue, col. 6, lines 34-40,59-62. Muhanna additionally

discloses various components or materials are interchangeable within the concept of the invention, col. 7, lines 27-30. With respect to claim 39, Fig. 3A shows a folded configuration of the implant material **14** with a drawstring **15** attached to the implant material. Fig. 4B also shows the implant material with a folded configuration that is implanted in the vertebrae. Please note the functional recitations (in claims 40,41) “for folding” and “in a manner to facilitate folding” have not been given patentable weight because the functional recitations must be supported by recitation in the claim of sufficient structure and steps to warrant the presence of the functional language.

Claims 1,2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bohan et al. (5279539). Bohan et al. disclose a device (Fig. 6) for tissue augmentation comprising a length of tissue **11** and drawstrings **30,31** for pulling or folding the device up. Bohan et al. also disclose the material for the device 11 is derived from biological tissue, such as cellulose, col. 5, lines 41,46,47,51,52. Please note the intended use carries no weight in the absence of any distinguishing structure.

Claims 1-3,12,34,35,38 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurland (4585458). Kurland discloses a device (Fig. 12) for tissue augmentation comprising drawstrings **84** and a length of tissue graft **80**. Kurland also discloses the graft comprises pericardium, col. 4, lines 4-6. Fig. 26 shows the graft **136** can be braided and has at least three strands **137**. Please note the intended use carries no weight in the absence of any distinguishing structure.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muhanna '070 in view of Sybert et al. (2002/107570). Muhanna is explained above. However, Muhanna fails to disclose the graft tissue is SIS. Sybert et al. discloses that natural tissue (small intestine submucosa) can be used to form a prosthetic device, paragraph 31. It would have been obvious to one of ordinary skill in the art to utilize SIS as taught by Sybert et al. for the graft tissue in Muhanna's prosthetic device because of the abundance of SIS and its durability.

***Allowable Subject Matter***

Claims 42-48 are allowed.

***Response to Arguments***

Applicant's arguments filed 11/21/06 have been fully considered but they are not persuasive. In response to applicant's argument that Muhanna fails to disclose a drawstring effective to fold the device after implantation, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (7:30am-5pm) and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

**BRIAN E. PELLEGRINO**  
**PRIMARY EXAMINER**

A handwritten signature in black ink that reads "Brian E. Pellegrino". The signature is written in a cursive style with a large, stylized "B" and "P".